

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Walsh et al. Confirmation No.: Not Assigned
Appl No.: Not Assigned Group Art Unit: Not Assigned
Filed: October 9, 2003 Examiner: Not Assigned
For: ADENO-ASSOCIATED VIRUS VECTORS ENCODING
FACTOR VIII AND METHODS OF USING THE SAME

Mail Stop Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

COMMUNICATION
REGARDING INFORMATION DISCLOSURE STATEMENT
MAILED OCTOBER 9, 2003

Applicants wish to call the Examiner's attention to claim 1 of U.S. Patent No. 6,200,560, which is listed as Cite Number 19 on the Information Disclosure Statement mailed October 9, 2003, for the present application. Applicants note that claim 1 of the present application is identical to claim 1 of U.S. Patent No. 6,200,560.

Respectfully submitted,

Kathryn L. Coulter

Kathryn L. Coulter
Registration No. 45,889

Customer No. 00826
ALSTON & BIRD LLP
Bank of America Plaza
101 South Tryon Street, Suite 4000
Charlotte, NC 28280-4000
Tel Raleigh Office (919) 862-2200
Fax Raleigh Office (919) 862-2260

CERTIFICATE OF EXPRESS MAILING

"Express Mail" mailing label number EV185285374US.

Date of Deposit October 9, 2003

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to Mail Stop Patent Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

Nora C. Martinez
Nora C. Martinez

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Walsh et al. Confirmation No.: Not Assigned
Appl No.: Not Assigned Group Art Unit: Not Assigned
Filed: October 9, 2003 Examiner: Not Assigned
For: ADENO-ASSOCIATED VIRUS VECTORS ENCODING
FACTOR VIII AND METHODS OF USING THE SAME

Mail Stop Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT
CITATION UNDER 37-C.F.R. § 1.97

Attached is a list of documents on form PTO-1449.

It is requested that the Examiner consider these documents and officially make them of record in accordance with the provisions of 37 C.F.R. § 1.97 and Section 609 of the MPEP. By submitting the listed documents, Applicant in no way makes any admission as to the prior art status of the listed documents, but is instead submitting the listed documents for the sake of full disclosure.

Any foreign patents or non-patent literature documents items are attached, except those that were supplied in, or cited by the Office during prosecution of, parent Application No. 09/689,430 filed October 12, 2000. Since the benefit of this application was claimed under 35 U.S.C. 120, no copies need to be furnished in accordance with 37 C.F.R. 1.98(d); however, copies will be furnished on request.

Respectfully submitted,

Kathryn L. Coulter

Kathryn L. Coulter
Registration No. 45,889

Customer No. 00826
ALSTON & BIRD LLP
Bank of America Plaza
101 South Tryon Street, Suite 4000
Charlotte, NC 28280-4000
Tel Raleigh Office (919) 862-2200
Fax Raleigh Office (919) 862-2260

CERTIFICATE OF EXPRESS MAILING

"Express Mail" mailing label number EV185285374US

Date of Deposit October 9, 2003

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to Mail Stop Patent Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 .

Nora C. Martinez
Nora C. Martinez

Substitute for form 1449/PTO (Revised 04/2003) INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	Not Assigned
				Filing Date	October 9, 2003
				First Named Inventor	Walsh et al.
				Group Art Unit	Not Assigned
Examiner Name	Not Assigned				
Sheet	1	of	6	Attorney Docket Number	035052/270239

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No.	Document Number Number - Kind Code (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages of Relevant Figures Appear
	1	US-5,587,308 A	12-24-1996	Carter et al.	All
	2	US-5,633,150 A	05-27-1997	Wood et al.	All
	3	US-5,658,785 A	08-19-1997	Johnson	All
	4	US-5,658,776 A	08-19-1997	Flotte et al.	All
	5	US-5,661,008 A	08-26-1997	Almstedt et al.	All
	6	US-5,744,326	04-28-1998	Ill et al.	All
	7	US-5,750,172	05-12-1998	Meade et al.	All
	8	US-5,837,484 A	11-17-1998	Trempe et al.	All
	9	US-5,843,742	12-01-1998	Natsoulis et al.	All
	10	US-5,856,152	01-05-1999	Wilson et al.	All
	11	US-5,858,775	01-12-1999	Johnson	All
	12	US-5,866,696	02-02-1999	Carter et al.	All
	13	US-5,871,986	02-16-1999	Boyce	All
	14	US-5,880,327	03-09-1999	Lubon et al.	All
	15	US-5,885,971	03-23-1999	German et al.	All
	16	US-5,935,935 A	08-10-1999	Connelly et al.	All
	17	US-5,990,279 A	11-23-1999	Carter et al.	All
	18	US-6,114,113 A	09-05-2000	McLaughlin-Taylor et al.	All
	19	US-6,200,560	03-13-2001	Couto et al.	All
	20	US-6,221,349 B1	04-24-2001	Coutou et al.	All
	21	US-6,255,289 B1	07-03-2001	German et al.	All
	22	US-6,258,595 B1	07-10-2001	Gao et al.	
	23	US-6,346,415 B1	02-12-2002	Feldhaus	All
	24	US-6,436,392 B1	08-20-2002	Engelhardt et al.	All
	25	US-2002/0151509 A1	10-17-2002	Snyder et al.	All

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute for form 1449/PTO (Revised 04/2003) INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	Not Assigned
				Filing Date	October 9, 2003
				First Named Inventor	Walsh et al.
				Group Art Unit	Not Assigned
				Examiner Name	Not Assigned
Sheet	2	of	6	Attorney Docket Number	035052/270239

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.	Foreign Patent Document Country Code - Number Kind Code (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	English Language Translation Attached
	26	WO 92/05273 A1	04-02-1992	The Regents of the University of Michigan	All	
	27	WO 92/22635 A1	12-23-1992	University of Connecticut	All	
	28	WO 93/24641 A2	12-09-1993	The United States of America as represented by The Secretary, Department of Health & Human Services	All	
	29	WO 94/06283 A1	03-31-1994	The Regents of the University of Michigan	All	
	30	WO 94/26915 A1	11-24-1994	The Regents of the University of Michigan	All	
	31	WO 94/28938 A1	12-22-1994	The Regents of the University of Michigan	All	
	32	WO 94/29471 A1	12-22-1994	Genetic Therapy, Inc.	All	
	33	WO 95/34670 A2	12-21-1995	Children's Hospital, Inc.	All	
	34	WO 96/09074 A1	03-28-1996	The General Hospital Corporation	All	
	35	WO 96/13597 A2	05-09-1996	The Trustees of the University of Pennsylvania	All	
	36	WO 96/13598 A2	05-09-1996	The Trustees of the University of Pennsylvania	All	
	37	WO 96/26285 A2	08-29-1996	The Trustees of the University of Pennsylvania and The Wistar Institute of Anatomy and Biology	All	
	38	WO 96/26286 A1	08-29-1996	The Trustees of the University of Pennsylvania	All	
	39	WO 96/39530 A2	12-12-1996	The Trustees of the University of Pennsylvania	All	
	40	WO 97/45550	12-04-1997	Zhang, W.		
	41	WO 98/00542 A2	01-08-1998	Chiron Corporation	All	
Examiner Signature					Date Considered	

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute for form 1449/PTO (Revised 04/2003) INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	Not Assigned
				Filing Date	October 9, 2003
				First Named Inventor	Walsh et al.
				Group Art Unit	Not Assigned
				Examiner Name	Not Assigned
Sheet	3	of	6	Attorney Docket Number 035052/270239	

FOREIGN PATENT DOCUMENTS						
	42	WO 98/09524	03-12-1998	Srivastava, A.		
	43	WO 98/09657 A3	03-12-1998	Trustees of the University of Pennsylvania	All	
	44	WO 98/10086 A1	03-12-1998	Trustees of the University of Pennsylvania	All	
	45	WO 98/11243 A2	03-19-1998	The General Hospital Corporation and Biogen	All	
	46	WO 98/12311 A2	03-26-1998	The General Hospital Corporation	All	
	47	WO 98/27204 A3	06-25-1998	Targeted Genetics Corporation	All	
	48	WO 99/11764 A2	03-11-1999	Targeted Genetics Corporation	All	
	49	WO 99/14354 A1	03-25-1999	The Trustees of the University of Pennsylvania	All	
	50	WO 99/15685 A1	04-01-1999	The Trustees of the University of Pennsylvania	All	
	51	WO 99/20773 A2	04-29-1999	Targeted Genetics Corporation	All	
	52	WO 99/20779 A1	04-29-1999	Targeted Genetics Corporation	All	
	53	WO 99/47691 A1	09-23-1999	Trustees of the University of Pennsylvania	All	
	54	WO 99/60146 A1	11-25-1999	University of Iowa Research Foundation	All	
	55	WO 99/61595 A2	12-02-1999	Cell Genesys, Inc.	All	
	56	WO 99/61642	12-02-1999	Snyder, R.		
	57	WO 00/14205 A3	03-16-2000	Targeted Genetics Corporation	All	
	58	WO 00/23116	04-27-2000	Couto, L.		
	59	WO 00/28061 A3	05-18-2000	The Trustees of the University of Pennsylvania	All	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute for form 1449/PTO (Revised 04/2003) INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	Not Assigned
				Filing Date	October 9, 2003
				First Named Inventor	Walsh et al.
				Group Art Unit	Not Assigned
Examiner Name	Not Assigned				
Sheet	4	of	6	Attorney Docket Number	035052/270239

FOREIGN PATENT DOCUMENTS						
	60	WO 00/55342 A1	09-21-2000	The Trustees of the University of Pennsylvania	All	
	61	WO 00/65038 A2	11-02-2000	Targeted Genetics Corporation	All	
	62	WO 00/73480 A1	12-07-2000	Genovo, Incorporated	All	
	63	WO 00/73481 A1	12-07-2000	Targeted Genetics Corporation	All	
	64	WO 00/75365 A2	12-14-2000	University of Iowa Research Foundation	All	
	65	WO 00/77233 A2	12-21-2000	The General Hospital Corporation	All	
	66	WO 01/11034 A2	02-15-2001	Targeted Genetics Corporation	All	
	67	WO 01/23597 A2	04-05-2001	The Trustees of the University of Pennsylvania	All	
	68	WO 01/25462 A1	04-12-2001	Genovo, Incorporated	All	
	69	WO 01/26565 A1	04-12-2001	University of Iowa Research Foundation	All	

OTHER DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	English Language Translation Attached
	70	BARTLETT <i>et al.</i> , "Genetics and Biology of Adeno-Associated Virus," <i>Viral Vectors, Gene Therapy and Neuroscience Applications</i> (1995), pp. 55-73, Edited by Kaplitt and Loewy, Academic Press, Inc.	
	71	BARTLETT, J.S. and SAMULSKI, R.J., "Adeno-Associated Virus Vectors for Human Gene Therapy," <i>Gene Therapy</i> , 1996, pp. 72-92, Bios Scientific Publishers Ltd., Oxford, UK	
	72	BURKE, R.L., et al., "The Functional Domains of Coagulation Factor VII:C," <i>The Journal of Biological Chemistry</i> , September 25, 1996, pp. 12574-12578, Vol. 216, No. 27	
	72	BURTON, M., et al., "Coexpression of Factor VIII Heavy and Light Chain Adeno-associated Viral Vectors Produces Biologically Active Protein," <i>PNAS</i> , October 26, 1999, pp. 12725-12730, Vol. 96, No. 22	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute for form 1449/PTO (Revised 04/2003) INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	Not Assigned
				Filing Date	October 9, 2003
				First Named Inventor	Walsh et al.
				Group Art Unit	Not Assigned
				Examiner Name	Not Assigned
Sheet	5	of	6	Attorney Docket Number	035052/270239

OTHER DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	English Language Translation Attached
	74	CHAO, H., et al., Sustained Expression of Human Factor VIII in Mice Using a Parvovirus-Based Vector (2000) Blood, Vol. 95(5), pp. 1594-1599	
	75	CHUAH <i>et al.</i> , "Gene Therapy for Hemophilia: Hopes and Hurdles," <i>Critical Reviews in Oncology/Hematology</i> (1998) Vol. 28, pp. 153-171	
	76	CONNELLY <i>et al.</i> , "Sustained Expression of Therapeutic Levels of Human Factor VIII in Mice," <i>Blood</i> , June 1, 1996, Vol. 87, No. 11, pp. 4671-4677	
	77	CONNELLY <i>et al.</i> , "Complete Short-Term Correction of Canine Hemophilia A by In Vivo Gene Therapy," <i>Blood</i> , November 15, 1996, Vol. 88, No. 10, pp. 3846-3853	
	78	CONNELLY <i>et al.</i> , "Sustained Phenotypic Correction of Murine Hemophilia A by In Vivo Gene Therapy," <i>Blood</i> , May 1, 1998, Vol. 91, No. 9, pp. 3273-3281	
	79	DONG <i>et al.</i> , "Quantitative Analysis of the Packaging Capacity of Recombinant Adeno-Associated Virus," <i>Human Gene Therapy</i> , November 10, 1996, Vol. 7, pp. 2111-2112	
	80	DWARKI <i>et al.</i> , "Gene Therapy for Hemophilia A: Production of Therapeutic Levels of Human Factor VIII in Vivo in Mice," <i>Proc. Natl. Acad. Sci. USA</i> , February 1995, Vol. 92, pp. 1023-1027	
	81	FLOTTE, T.R., et al., "Expression of the Cystic Fibrosis Transmembrane Conductance Regulator from a Novel Adeno-associated Virus Promoter," <i>The Journal of Biological Chemistry</i> , February 15, 1993, pp. 3781-3790, Vol. 268, No. 5	
	82	GNATENKO, D., et al., "Generation and Characterization of Recombinant Adeno-associated Viral (rAAV) Vectors for Factor VIII Gene Therapy," <i>Blood</i> , November 15, 1996, Vol. 88, No. 10, Supplement I, Abstract No. 543-1	
	83	GNATENKO, D., et al., "Recombinant Adeno-associated Virus as a Vehicle for Gene Delivery of Human Mutant Factor VIII," <i>Blood</i> , November 15, 1997, Vol. 90, No. 10, Supplement 1 (Part 1 of 2), Abstract No. 518-1	
	84	GNATENKO <i>et al.</i> , "Human Factor VIII can be Packaged and Functionally Expressed in an Adeno-Associated Virus Background: Applicability to Haemophilia A Gene Therapy," <i>British Journal of Haematology</i> , 1999, Vol. 104, pp. 27-36	
	85	HERZOG <i>et al.</i> , "Problems and Prospects in Gene Therapy for Hemophilia," <i>Current Opinion in Hematology</i> , 1998, pp. 321-326	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute for form 1449/PTO (Revised 04/2003) INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	Not Assigned
				Filing Date	October 9, 2003
				First Named Inventor	Walsh et al.
				Group Art Unit	Not Assigned
Examiner Name	Not Assigned				
Sheet	6	of	6	Attorney Docket Number	035052/270239

OTHER DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	English Language Translation Attached
	86	ILL, C., et al., Optimization of the Human Factor VIII Complementary DNA Expression Plasmid for Gene Therapy of Hemophilia A (1997) Blood Coagulation & Fibrinolysis, Vol. 8(2), pp. S23-S30	
	87	KAY <i>et al.</i> , "In Vivo Gene Therapy of Hemophilia B: Sustained Partial Correction in Factor IX-Deficient Dogs," <i>Science</i> , October 1, 1993, Vol. 262, pp. 117-119	
	88	KAUFMAN, R.J., "Biosynthesis, Assembly and Secretion of Coagulation Factor VIII," <i>Blood Coagulation and Fibrinolysis</i> , 1997, pp. S3-S14, Vol. 8, Suppl. 2	
	89	KAUFMAN, R.J., "Advances Toward Gene Therapy for Hemophilia at the Millennium," <i>Human Gene Therapy</i> , September 1, 1999, pp. 2091-2107, Vol. 10	
	90	LAU, J.Y.N., and MUZYCZKA, N., "Adeno-Associated Virus (AAV) As a Gene Delivery Vector for Liver Cells," <i>Hepatology</i> , October 1997, Vol. 26, No. 4, Pt. 2, Abstract No. 273	
	91	LOZIER <i>et al.</i> , "Gene Therapy and the Hemophilias," <i>JAMA</i> , January 5, 1994, Vol. 271, No. 1, Pp. 47-51	
	92	RUSSELL <i>et al.</i> , "Adeno-Associated Virus Vectors and Hematology," <i>Blood</i> , August 1, 1999, Vol. 94, No. 3., pp. 864-874	
	93	SUGIYAMA, A., et al., "Development of a Defective Adeno-Associated Viral Vector Construct for Translation and Expression of Insulin Gene in Liver Cells In Vitro and In Vivo," <i>Diabetes Abstract Book</i> , May 1995, p. 128A, Vol. 44, Suppl. 1, Abstract No. 470	
	94	WANG, L, et al., Sustained Correction of Bleeding Disorder in Hemophilia B Mice by Gene Therapy (1999) Proc. Natl. Acad. Sci. USA Vol. 96, pp. 3906-3910	
	95	YONEMURA, H., et al., "Efficient Production of Recombinant Human Factor VIII by Co-expression of the Heavy and Light Chains," <i>Protein Engineering</i> , 1993, pp. 669-674, Vol. 6, No. 6	

RTA01/2143992v1

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.